PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 24 August 2000 (24.08.00)	
International application No. PCT/US99/22908	**Applicant's or agent's file reference** PF-0609 PCT
International filing date (day/month/year) 01 October 1999 (01.10.99)	**Priority date** (day/month/year) 02 October 1998 (02.10.98)
Applicant TANG, Y., Tom et al	

1. The designated Office is hereby notified of its election made:

   [X] in the demand filed with the International Preliminary Examining Authority on:

   27 April 2000 (27.04.00)

   [ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

   [ ] was not

   made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland** Facsimile No.: (41-22) 740.14.35	Authorized officer C. Cupello Telephone No.: (41-22) 338.83.38

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 :
C12N 15/12, C07K 14/47, G01N 33/50, C12Q 1/68, C07K 16/18, A61K 38/17

A3

(11) International Publication Number: **WO 00/20588**

(43) International Publication Date: 13 April 2000 (13.04.00)

(21) International Application Number: PCT/US99/22908

(22) International Filing Date: 1 October 1999 (01.10.99)

(30) Priority Data:
09/165,621 2 October 1998 (02.10.98) US
Not furnished 2 October 1998 (02.10.98) US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Applications
US 09/165,621 (CIP)
Filed on 2 October 1998 (02.10.98)
US Not furnished (CIP)
Filed on 2 October 1998 (02.10.98)

(71) Applicant *(for all designated States except US)*: INCYTE PHARMACEUTICALS, INC. [US/US]; 3174 Porter Drive, Palo Alto, CA 94304 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: TANG, Y., Tom [CN/US]; 4230 Ranwick Court, San Jose, CA 95118 (US). CORLEY, Neil, C. [US/US]; 1240 Dale Avenue #30, Mountain View, CA 94087 (US). GUEGLER, Karl, J. [CH/US]; 1048 Oakland Avenue, Menlo Park, CA 94025 (US). LU, Dyung, Aina, M. [US/US]; 55 Park Belmont Place, San Jose, CA 95136 (US).

(74) Agents: BILLINGS, Lucy, J. et al.; Incyte Pharmaceuticals, Inc., 3174 Porter Drive, Palo Alto, CA 94304 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(88) Date of publication of the international search report:
6 July 2000 (06.07.00)

(54) Title: BONE MARROW-DERIVED SERUM PROTEINS

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1   MPAK------TPIYL-KAANNKKGKKFKLR  1859631
1   MPGPQGGRGAATMSLGKLSPVGWVSSSQGK  GI 338033

24  DILSPDMISPPLGDFRHTIHIGKEGQHDVF  1859631
31  RRLTADMISHPLGDFRHTMHVGRGG--DVF  GI 338033

54  GDISFLQGNYELLPGNQEKAHLGQFPGHNE  1859631
59  GDTSFL-SNHGGSSGSTHRSPRSFLAKKLQ  GI 338033

84  FFRANSTSDSVFTETPSPVLKNAISLPTIG  1859631
88  LVRRVGAPPRRMASPPAPSPAPPAISPII-  GI 338033

114 GSQALMLPLLSPVTFNSKQESFGPAKLPRL  1859631
117 -KNAISLPQLNQAAY----DSLVVGKLS-F  GI 338033
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(57) Abstract

The invention provides human bone marrow–derived serum proteins (BMDSP) and polynucleotides which identify and encode BMDSP. The invention also provides expression vectors, host cells, antibodies, agonists, and antagonists. The invention also provides methods for diagnosing, treating or preventing disorders associated with expression of BMDSP.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania
AM	Armenia
AT	Austria
AU	Australia
AZ	Azerbaijan
BA	Bosnia and Herzegovina
BB	Barbados
BE	Belgium
BF	Burkina Faso
BG	Bulgaria
BJ	Benin
BR	Brazil
BY	Belarus
CA	Canada
CF	Central African Republic
CG	Congo
CH	Switzerland
CI	Côte d'Ivoire
CM	Cameroon
CN	China
CU	Cuba
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
ES	Spain
FI	Finland
FR	France
GA	Gabon
GB	United Kingdom
GE	Georgia
GH	Ghana
GN	Guinea
GR	Greece
HU	Hungary
IE	Ireland
IL	Israel
IS	Iceland
IT	Italy
JP	Japan
KE	Kenya
KG	Kyrgyzstan
KP	Democratic People's Republic of Korea
KR	Republic of Korea
KZ	Kazakstan
LC	Saint Lucia
LI	Liechtenstein
LK	Sri Lanka
LR	Liberia
LS	Lesotho
LT	Lithuania
LU	Luxembourg
LV	Latvia
MC	Monaco
MD	Republic of Moldova
MG	Madagascar
MK	The former Yugoslav Republic of Macedonia
ML	Mali
MN	Mongolia
MR	Mauritania
MW	Malawi
MX	Mexico
NE	Niger
NL	Netherlands
NO	Norway
NZ	New Zealand
PL	Poland
PT	Portugal
RO	Romania
RU	Russian Federation
SD	Sudan
SE	Sweden
SG	Singapore
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SK	Slovakia
SN	Senegal
SZ	Swaziland
TD	Chad
TG	Togo
TJ	Tajikistan
TM	Turkmenistan
TR	Turkey
TT	Trinidad and Tobago
UA	Ukraine
UG	Uganda
US	United States of America
UZ	Uzbekistan
VN	Viet Nam
YU	Yugoslavia
ZW	Zimbabwe

INTERNATIONAL SEARCH REPORT

I Application No
PCT/US 99/22908

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12N15/12 C07K14/47 G01N33/50 C12Q1/68 C07K16/18
A61K38/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12N C07K G01N C12Q A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 592 230 A (SNOW BRAND MILK PROD CO LTD) 13 April 1994 (1994-04-13) the whole document ---	1,2, 4-11,15, 16,19
A	BAHOU, W.F. ET AL.: "cDNA cloning and molecular characterization of MSE55, a novel human serum constituent protein that displays bone marrow stromal/endothelial cell-specific expression." JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 267, no. 20, 1992, pages 13986-92, XP002128573 cited in the application the whole document -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 January 2000	02. 05. 2000
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Smalt, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/ 22908

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see additional sheet, subject 1.

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box 3.

Although claims 19 and 20 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Further defect(s) under Article 17(2)(a):

Continuation of Box 3.

Claims Nos.: 17,18,20

A meaningful search of claims 17, 18 and 20, relating to an agonist, respectively an antagonist of the polypeptide of the invention, was not possible due to insufficient characterization of the (ant)agonist in the description (lack of disclosure, Art. 5 PCT, and lack of support, Art. 6 PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-20, all partially

The protein referred to in the description as 1859631 or Bone marrow-derived serum protein 1 (BMDSP-1) and nucleic acids encoding it, homologs and complements thereof, method for detecting the polynucleotide, expresison vector, host cell, method for producing, antobody against said protein, and use of said protein for the preparation of a pharmaceutical composition.

2. Claims: 1-20, all partially

The protein referred to in the description as GI338033 or Bone marrow-derived serum protein 2 (BMDSP-2) and nucleic acids encoding it, homologs and complements thereof, method for detecting the polynucleotide, expresison vector, host cell, method for producing, antobody against said protein, and use of said protein for the preparation of a pharmaceutical composition.

INTERNATIONAL SEARCH REPORT

Information on patent family members

[redacted] al Application No
PCT/US 99/22908

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0592230 A	13-04-1994	JP 6113881 A	26-04-1994
		AU 4889393 A	21-04-1994
		CA 2107761 A	08-04-1994
		ZA 9307451 A	07-04-1995

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
PF-0609 PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 99/ 22908	01/10/1999	02/10/1998

Applicant

INCYTE PHARMACEUTICALS, INC. et al.

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   ☒ contained in the international application in written form.

   ☒ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readble form.

   ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 3a

   ☐ None of the figures.

   ☐ as suggested by the applicant.

   ☐ because the applicant failed to suggest a figure.

   ☒ because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/ 22908

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see additional sheet, subject 1.

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box 3.

Although claims 19 and 20 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Further defect(s) under Article 17(2)(a):

Continuation of Box 3.

Claims Nos.: 17,18,20

A meaningful search of claims 17, 18 and 20, relating to an agonist, respectively an antagonist of the polypeptide of the invention, was not possible due to insufficient characterization of the (ant)agonist in the description (lack of disclosure, Art. 5 PCT, and lack of support, Art. 6 PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-20, all partially

The protein referred to in the description as 1859631 or Bone marrow-derived serum protein 1 (BMDSP-1) and nucleic acids encoding it, homologs and complements thereof, method for detecting the polynucleotide, expresison vector, host cell, method for producing, antobody against said protein, and use of said protein for the preparation of a pharmaceutical composition.

2. Claims: 1-20, all partially

The protein referred to in the description as GI338033 or Bone marrow-derived serum protein 2 (BMDSP-2) and nucleic acids encoding it, homologs and complements thereof, method for detecting the polynucleotide, expresison vector, host cell, method for producing, antobody against said protein, and use of said protein for the preparation of a pharmaceutical composition.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/22908

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12N15/12 C07K14/47 G01N33/50 C12Q1/68 C07K16/18
A61K38/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12N C07K G01N C12Q A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 592 230 A (SNOW BRAND MILK PROD CO LTD) 13 April 1994 (1994-04-13) the whole document ---	1,2, 4-11,15, 16,19
A	BAHOU, W.F. ET AL.: "cDNA cloning and molecular characterization of MSE55, a novel human serum constituent protein that displays bone marrow stromal/endothelial cell-specific expression." JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 267, no. 20, 1992, pages 13986-92, XP002128573 cited in the application the whole document -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 January 2000	02. 05. 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smalt, R

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 99/22908

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0592230 A	13-04-1994	JP 6113881 A	26-04-1994
		AU 4889393 A	21-04-1994
		CA 2107761 A	08-04-1994
		ZA 9307451 A	07-04-1995

09/806276

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference PF-0609 PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/22908	International filing date *(day/month/year)* 01 OCTOBER 1999	Priority date *(day/month/year)* 02 OCTOBER 1998
International Patent Classification (IPC) or national classification and IPC IPC(7): C07K 15/00; C12P 21/08; A61K 39/395 and US Cl.: 536/23.1; 530/350		
Applicant INCYTE GENOMICS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☒ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☐ Certain observations on the international application

Date of submission of the demand 27 APRIL 2000	Date of completion of this report 15 SEPTEMBER 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer HOPE ROBINSON Telephone No. (703) 308-0196

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/22908

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-52 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the claims:
pages 53-54 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the drawings:
pages 1-11 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/22908

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-20 in part

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination *(specify)*.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _ are so unclear that no meaningful opinion could be formed *(specify)*.

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. Claims 1-20 in part .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/22908

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

Please See Supplemental Sheet.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☐ all parts.

   ☐ the parts relating to claims Nos. .

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/22908

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	NONE	YES
	Claims	1-15 (SEQ ID NO: 2)	NO
Inventive Step (IS)	Claims	NONE	YES
	Claims	1-15 (SEQ ID NO: 2)	NO
Industrial Applicability (IA)	Claims	1-15 (SEQ ID NO: 2)	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 1-15 lack an novelty under PCT Article 33(2) as being anticipated by SNOW BRAND MILK PRODUCTS & CO. LTD.

In view of the International Search Report, the reference discloses human monoclonal antibody directed against a peptide which exists in the CH4 region of human IgE and is related to signal transduction of chemical mediator release f rom sensitized mast cells and basophils. The monoclonal antibody inhibits the histamine release from mast cells by stimulation with allergen. Moreover the reference discloses that as the antibody recognizes a specific amino acid sequence relates to allergic reactions, this antibody is useful as medicines and reagents. Further, the reference apparently discloses a sequence (SEQ ID No: 2) that has a high homology to the sequence set forth in SEQ ID No: 1 of the instant application. Therefore, the limitations of the claims are met by this reference. It is noted that the International Examination Authority lacks a computer readable form of the sequence listing, so sequence alignment was not performed.

Claims 1-15 lack an inventive step under PCT Article 33(3) as being obvious over SNOW BRAND MILK PRODUCTS & CO. LTD. The teachings of the reference are above as the reference anticipates the claimed invention. Since the claims are anticipated they are also lack an inventive step.

Claims 1-15 meet the criteria for industrial applicability under PCT Article 33(4).

---------- NEW CITATIONS ----------
NONE

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

IV. LACK OF UNITY OF INVENTION:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2, and 13.3 is not complied with for the following reasons:

As applicant was previously notified this International Preliminary Examining Authority has found plural inventions claimed in the International Application covered by the claims indicated below:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-15, drawn to a bone marrow derived serum protein 1 (BMDSP-1), polynucleotide encoding said protein, method of detecting said polynucleotide, expression vector, host cell and method of recombinant production of BMDSP-1.
Group II, claim(s) 1-15, drawn to a bone marrow derived serum protein 2 (BMDSP-2), polynucleotide encoding said protein, method of detecting said polynucleotide, expression vector, host cell and method of recombinant production of BMDSP-2.
Group III, claim 16, drawn to an antibody that specifically binds to BMDSP-1.
Group IV, claim 16, drawn to an antibody that specifically binds to BMDSP-2.
Group V, claim 17, drawn to an agonist of BMDSP-1.
Group VI, claim 17, drawn to an agonist of BMDSP-2.
Group VII, claim 18, drawn to an antagonist of BMDSP-1.
Group VIII, claim 18, drawn to an antagonist of BMDSP-2.
Group IX, claim 19, drawn to a method of treating or preventing a disorder associated with decreased expression or activity of BMDSP-1.
Group X, claim 19, drawn to a method of treating or preventing a disorder associated with decreased expression or activity of BMDSP-2.
Group XI, claim 20, drawn to a method of treating or preventing a disorder associated with increased expression or activity of BMDSP-1.
Group XII, claim 20, drawn to a method of treating or preventing a disorder associated with increased expression or activity of BMDSP-2.

and it considers that the International Application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated below:

The inventions listed as Groups I-XII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claim 1 recites the technical feature of a polypeptide comprising a fragment of SEQ ID NO:1. EP 0592230 A1 cited on the International Search Report teach polypeptide sequence which comprise a fragment of SEQ ID NO:1, where the fragment is a 'leucine' residue, f or example. In view of the open claim language 'comprising' and the lack of other structural or functional limitations, the amino acid sequences in EP0592230 A1 read upon claim 1. Thus, the technical feature of claim 1 is not special.

The polypeptides, nucleic acid molecules, vectors and host cells of Groups I/II are related to the antibodies of Groups III/IV by virtue of the polypeptide being the cognate antigen necessary for the production of the antibodies. Although the polypeptide and antibody are related due to the necessary stearic complementarity of the two, they are distinct Inventions because the polypeptide can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right or in assays for identification of agonists or antagonists of the polypeptide. Groups I/II are unrelated to the agonists of Group V/VI because they differ structurally. Groups I/II are unrelated to the antagonists of Groups VII/VIII because they differ in function and in structure. Groups I/II are related to Groups IX/X in that it can be used in the method of Groups IX/X, however, the polypeptides, for instance, can also be used in the materially different process of antibody production. Groups I/II are unrelated to Groups XI/XII in that the former is not used in the latter. Groups III/IV are unrelated to Groups V/VI, VII/VIII, IX/X and XI/XII. Groups V/VI are unrelated to Groups VII/VIII in that they differ functionally and structurally. Groups V/VI are related to the methods of Groups IX/X, however, the former can also be used in assays. Groups V/VI are unrelated to the methods of Groups XI/XII. Groups VII/VIII are unrelated to the methods of Groups IX/X. Groups VII/VIII are related to the methods of Groups XI/XII, however, the former can also be used in assays. Groups IX/X and XI/XII are unrelated to each other since the methods employ different compositions and have opposite outcomes.

Groups I-XII do not related to a single inventive concept under PCT Rule 13.1.